



Daiichi Sankyo, Lilly Submit New Drug Application for Investigational Antiplatelet Drug, Prasugrel, with U.S. Food and Drug Administration

If Approved for Marketing in the United States, Trade Name Will be Effient(TM)

TOKYO and INDIANAPOLIS, Jan 04, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Daiichi Sankyo Company, Limited (TSE: 4568) and Eli Lilly and Company (NYSE: LLY) today announced that on Wednesday, Dec. 26, 2007, they submitted a New Drug Application (NDA) for prasugrel to the U.S. Food and Drug Administration (FDA). Prasugrel is an oral antiplatelet agent, initially in development for the treatment of patients with acute coronary syndrome (ACS) who are managed with percutaneous coronary intervention (PCI), including coronary stenting.

If approved for marketing in the United States, the trade name for prasugrel will be Effient(TM), company officials added.

"We are elated," said J. Anthony Ware, M.D., Lilly vice president and cardiovascular/acute care platform leader for prasugrel. "We feel confident in the strength and completion of this submission package, and plan to complete our submission in Europe in the first quarter of 2008. The benefit/risk profile of this compound, in comparison with the current standard of care, has the potential to improve outcomes for ACS patients undergoing PCI."

The NDA is based upon data from several trials, including the landmark TRITON-TIMI 38 clinical trial, which evaluated the safety and efficacy of prasugrel compared with clopidogrel (Plavix(R)/Iscover(R)) in reducing ischemic events such as non-fatal heart attack, non-fatal stroke and cardiovascular death in 13,608 patients. In the study, treatment with prasugrel resulted in a:

- 19 percent relative risk reduction compared with clopidogrel in all ACS patients in the primary composite endpoint of non-fatal heart attack, non-fatal stroke or cardiovascular death ($p < 0.001$).
- 52 percent reduction compared with clopidogrel in stent thrombosis ($p < 0.0001$).
- 30 percent relative risk reduction compared to clopidogrel in a subset of patients with diabetes ($p < 0.001$) on the composite endpoint of non-fatal heart attack, non-fatal stroke, or cardiovascular death.

Risk reductions in the primary composite endpoint with prasugrel compared to clopidogrel were seen as early as three days and continued to diverge for 15 months (the duration of the trial.)

Though the incidence of non-coronary artery bypass grafting(non-CABG) bleeding in TRITON was low in both the prasugrel and clopidogrel treatment groups, prasugrel-treated patients experienced significantly higher non-CABG major bleeding (2.2% vs. 1.7%, respectively) and higher rates of life-threatening bleeding (1.3% vs. 0.8%, respectively). Death from cardiovascular causes (2% vs. 2.2%, respectively) and all-cause death (2.8% vs. 2.9%, respectively) was comparable among prasugrel-treated patients and clopidogrel-treated patients. The overall results demonstrated that for every 1,000 patients treated with prasugrel as compared with clopidogrel, there were 22 fewer patients with heart attacks and five more non-CABG-related TIMI major bleeds.

"Given the overall results from TRITON, this submission is particularly meaningful considering that cardiovascular disease is the leading cause of death in the United States and worldwide, killing 16.7 million people each year," said John Alexander, M.D., M.P.H., global head of research and development, Daiichi Sankyo Company, Limited.

Acute heart attacks and unstable angina, called acute coronary syndrome, affect more than 840,000 Americans each year and 800,000 people in Europe.(i,ii) Utilizing current medical interventions and treatments, 300,000 people continue to experience recurrent heart attacks and 450,000 people die from heart attacks annually in the U.S.(iii)

About prasugrel

Daiichi Sankyo Company, Limited (TSE: 4568), and Eli Lilly and Company (NYSE: LLY) are co-developing prasugrel, an investigational oral antiplatelet agent invented by Daiichi Sankyo and its Japanese research partner Ube Industries, Ltd., as a potential treatment, initially for patients with acute coronary syndrome who are managed with PCI. Prasugrel works by inhibiting platelet activation and subsequent aggregation by blocking the P2Y12 adenosine diphosphate (ADP) receptor on the platelet surface. Antiplatelet agents prevent platelets from clumping or sticking together, which can result in clogged arteries and may lead to heart attack or stroke.

About Daiichi Sankyo Company, Limited

Daiichi Sankyo Company, Limited, established in 2005 after the merger of two leading century-old Japanese pharmaceutical companies, is a global pharmaceutical innovator, continuously generating innovative drugs that enrich the quality of life for patients around the world. The company uses its cumulative knowledge and expertise in the fields of cardiovascular disease, cancer, metabolic disorders, and infection as a foundation for developing an abundant product lineup and R&D pipeline.

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of first in class and best-in-class pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers - through medicines and information - for some of the world's most urgent medical needs.

This press release contains certain forward-looking statements about the potential of the investigational compound prasugrel (CS-747, LY640315) and reflects Daiichi Sankyo's and Lilly's current beliefs. However, as with any pharmaceutical compound under development, there are substantial risks and uncertainties in the process of development and regulatory review. There is no guarantee that the compound will receive regulatory approval, that the regulatory approval will be for the indication(s) anticipated by the companies, or that later studies and patient experience will be consistent with study findings to date. There is also no guarantee that the compound will prove to be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's filing with the United States Securities and Exchange Commission and Daiichi Sankyo's filings with the Tokyo Stock Exchange. Daiichi Sankyo and Lilly undertake no duty to update forward- looking statements.

Plavix(R)/Iscover(R) are registered trademarks of Sanofi-Synthelabo Inc. Effient(TM) is a trademark of Eli Lilly and Company.

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- (i) American Heart Association. Heart Disease and Stroke Statistics - 2006 Update. Dallas, TX. American Heart Association.
- (ii) Bertrand CURE study
- (iii) American Heart Association. Heart Attack and Angina Statistics.
URL: <http://www.americanheart.org/presenter.jhtml?identifier=4591>.
Last accessed July 26, 2007.

(Logo: <http://www.newscom.com/cgi-bin/prnh/20061120/DSLLOGO>)

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